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Carol W. Burton			PRATT, HELEN F		
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# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/067,515 Filing Date: February 04, 2002

Appellant(s): LEDERMAN, STEVEN

Carol Burton For Appellant

#### **EXAMINER'S ANSWER**

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This is in response to the appeal brief filed 5-5-04.

# (1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

# (2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

#### (3) Status of Claims

#### (3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

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#### (4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

## (5) Summary of Invention

The summary of invention contained in the brief is correct.

#### (6) Issues

The appellant's statement of the issues in the brief is correct.

## (7) Grouping of Claims

Appellant's brief includes a statement that claims 21-60 do stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

## (8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

## (9) Prior Art of Record

5,028,446	SALEEB et al.	7-1991
5,468,506	ANDON	11-1995
5,500,232	KEATING	3-1996
WO 92/1951	ANDON et al.	12-1992

# (10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-26, 27, 29, 31, 32, 39, 41, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saleeb et al. (Saleeb).

Saleeb et al. disclose as in claims 21, 26 and 27 a method of making a calcium containing product by making a suspension of CaOH in water and making a slurry of fumaric acid and water and combining the calcium containing aqueous suspension with the fumaric acid containing slurry under shear conditions at temperatures not over 160 F. and drying the mixture (abstract and col. 4, lines 16-34). A spray-dried product as in part ii is disclosed. The product is considered to contain solubilized calcium having improved organoleptic properties and enhanced rate of solubilization because the same process is used which would also make for an amorphous structure.

The calcium mixture is incorporated into a beverage such as tea as in claims 22 and 25 (col. 7, lines 1-9).

The powder is incorporated into gelatin as in claim 23 (col. 7, lines 24-45).

Vacuum drying, spray, drum oven and with or without vacuum drying the calcium product is disclosed by Saleeb et al. as in claim 31 (col. 3, lines 48-54).

The composition of Saleeb et al. is considered to be fiber-free as in claim 39 (abstract).

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As the method has been disclosed above the product is considered to have been shown as in claim 41.

The product combined with water to make a liquid supplement is disclosed in col. 4, lines 47-55 as in claim 42.

Claims 21, 22, 23, 25, 26, 27, 31, 39, 41, 42 differ from the reference, in that by fully solubilizing the aqueous calcium slurry in an aqueous acid solution that a dried solubilized calcium product having an amorphous structure is made (claim 21 in particularly). However, Saleeb et al. also fully solubilize their aqueous solution containing calcium in an aqueous acid solution because they also mix ingredients as Appellant does (col. 2, lines 1-55). Even though Appellant states that his product is amorphous, no limitations have been put into the claims to achieve such a product and to define over the reference. Nothing in the form of a showing has been presented to show that Appellant's product is more amorphous than that of the reference, which only discloses "generally crystalline" (col. 2, lines 14-18). Therefore, it would have been obvious to make a product, which would be as amorphous as shown by the process to Saleeb et al.

Claim 24 requires solubilizing the dried compound in water. Saleeb et al. disclose adding the composition to water to make a beverage, i. e. solubilizing the compound, which can be a tea drink (claim 25) (col. 7, lines 5-21). Nothing new is seen in packaging the product in a sealed container because beverages in containers are well known. As the method of making the composition has been shown, the product would have had the claimed shelf life of 6 months. The composition is seen to be amorphous,

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as the process has been shown. Therefore, it would have been obvious to package a product in a container and to make a product with a shelf life of six months.

Claim 29 requires that the temperature be attained by an exothermic reaction-taking place during acidification of the slurry. Saleeb et al. disclose that the reaction can be exothermic depending on the reactants. When calcium hydroxide is used the reaction is exothermic (col. 6, lines 40-60). Therefore, it would have been obvious to have an exothermic reaction depending on the reactants.

Claim 32 requires that the calcium compound is freeze - dried. Saleeb et al. disclose that various means of drying can be used (col. 3, lines 48-54). Certainly, freeze drying is another well known method of drying and nothing new is seen in its use. Therefore, it would have been obvious to freeze dry the product.

Claims 28, 30, 33-38, 40, 43-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saleeb et al. as applied to the above claims, and further in view of Andon WO 92/19251 and Keating (5,500,232).

It is noted that Andon WO92/19251 was discussed in the last office action, but that the correct serial number and inventor was omitted in the claims rejected over such and such section (FP 7.21). See office action dated 3-28-03, page 5 under the rejection of claims 28-30,33-38, 40, 43-60. This reference was first submitted by Appellant.

Claim 28 further requires that the aqueous solution attain a temperature of at least 170 F. Andon et al. '251 disclose a process of making a nutritional mineral supplement containing calcium citrate malate by dissolving citric acid and malic acid in water, heating to 131 F. while stirring, then adding calcium carbonate which has been

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combined with water at a pH of 4.3, and then dried (page 20, last para. and page 21 top paragraph). The reference discloses that reaction temperatures of from 30 to 80 C can be used, which are within the claimed range (page 12, lines 5-9). Raising the temperature as in claim 28 is seen as within the skill of the ordinary worker in order to solubilize and saturate the water solution as it is known to heat to at least 131 F. in order to solubilize the mixture as in claim 26. Keating discloses that it is known to heat calcium compounds such as calcium glycerophosphate and calcium hydroxide at no heat, and at 60 and 68 C. and also that the particular acid affects the solubility of the calcium (col. 7, lines 1-50). The heat treatments at 140 F. and above allowed the calcium to stay in suspension (col. 7, lines 11-17 and col. 8, Table I). Therefore, it would have been obvious to heat the mixture in the process Saleeb et al. to the claimed temperature because Andon et al. disclose heating within the claimed range and Keating discloses that heating certain calcium compounds improves their solubility (Table 1).

Claim 30 requires using external heat during acidification of the aqueous slurry. Keating discloses that various heating temperatures can be used which implies the use of external heat (col. 6, lines 60-70). Therefore, it would have been obvious to use external sources of heat in the process of the combined references.

Nothing new is seen in adding ingredients at any step of the process as in claim 33, especially as the ingredients are known. Therefore, it would have been obvious to add various ingredients to the composition.

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Claim 34 further requires that the process use various acids. Andon discloses the use of citric and malic acids (page 10, lines 14-16). Therefor, it would have been obvious to use the claimed acids in place of the fumaric acid of Saleeb et al.

Claim 35 further requires that the dried product is substantially amorphous. The products are seen to be substantially amorphous, as the claimed process has been shown and no other specific limitations are seen as to how to make the product amorphous. The product is further seen to be non-dendritic in morphology as in claim 36 for those reasons cited for claim 35. Therefore, it would have been obvious to make the product as amorphous as shown by the above references and non-dendritic.

Claims 37 and 38 further require particular minerals. Calcium and magnesium are from the same alkaline earth metal group and potassium and zinc are considered to be equivalents as to solubility characteristics since they are listed in the same group as calcium and magnesium. Therefore, it would have been obvious to use any one or two of the claimed minerals, as calcium has been shown.

Claim 40 further requires that the aqueous product does not form a precipitate for 6 months. As the process has been shown, it is seen that precipitates would not have been formed for 6 months. Also, Keating discloses no precipitation for 6 months (col. 9, Table 1). Therefore, it would have been obvious to make such a product.

Claims 43-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over the above combined references as applied to the above claims, and further in view of Andon (5,468,506).

Claim 43 requires the addition of other minerals and claim 44 the addition of sweeteners, flavors or colors. Andon discloses the addition of flavors and minerals in

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the composition (col. 9, lines 5-44, col. 2, lines 60-65, col. 3, lines 1-5). Therefore, it would have been obvious to add the claimed ingredients as shown by Andon '506.

Claim 45 further requires 250 mg of calcium in 8 oz of fluid. Andon discloses that the composition will contain a supplemental amount of from 10 to 300% of the RDA, which is seen to fall within the claimed amount (col. 2, lines 60-70). Therefore, it would have been obvious to provide the claimed amount of calcium in a beverage.

Claim 46 further requires that the supplement remain in solution for at least 6 months. As the process has been shown above in combination, it would have remained in solution for the claimed amount of time.

The limitations of claims 47-60 have been disclosed above and are obvious for those reasons except for the sweeteners of claims 54 and 58. Andon '506 discloses the addition of sweeteners to the composition (col. 12, lines 40-45). Therefore, it would have been obvious to add sweeteners to the composition.

## (11) Response to Argument

Appellant argues that the reference to Saleeb does not teach their claimed method, in that they first make an aqueous slurry containing calcium, then fully solubilize the aqueous slurry in an aqueous acid solution to produce a solution containing solubilized calcium, and then drying the solution to obtain an amorphous structure and that Saleeb teaches a method of making a generally crystalline structure (col. 1, lines 63-64). Saleeb teaches making a slurry of water and fumaric acid, and also a mixture of calcium hydroxide and water. The calcium hydroxide suspension was added slowly to the fumaric acid slurry at a temperature of 160 F. (col. 4, lines 16-34)

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and after stirring was vacuum dried. It is not seen how this process is different than the process of claim 21. Appellant argues that the reference to Saleeb et al. teach a method of making a generally crystalline structure (col. 1, lines 63-64) and this is done by a particular process (page 5, last full paragraph) and that large amounts of water are used to perfect crystal growth, and if the calcium fumarate is not a crystalline structure, it will not be soluble and will clump. Therefore, this composition is not an amorphous calcium product. However, it is not seen how the process claims distinguish over the reference and the Appellant's use of the word "amorphous" is seen to be a statement of intended results. Therefore, it is seen that the structure of the reference is as amorphous as the structure of the claims.

The significance of the argument that Saleeb first prepares an acid slurry which is not fully solubilizable" (col. 2, lines 42-48) is not seen because all claim 21 requires is making an "aqueous acid solution" which is combined with the calcium slurry and as above Saleeb does teach an aqueous acid solution (col. 24, lines 16-25).

Appellant argues that Saleeb teaches a method of making the product so that the product is crystalline. However, Appellants method does not require any particular order to define over Saleeb in the use of the term "comprising".

Appellant argues that even if the limitations of claims 21-27, 29, 32, 39, 41 and 42, 47-60 are met, that an amorphous product is not made in independent claim 26. The appellant also argues that Saleeb does not teach making an amorphous product and teaches away since Saleeb states that amorphous products are insoluble. Since the composition claims depend from the method claims, it is seen that the products of

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the method of the combined references are as amorphous as those made by the claimed methods. Where the claims are product by process claims, no showing has been made that the products are different. The fact that the procedures of the reference are different than that of applicant is not a sufficient reason for allowing the product-by-process claims since the patentability of such claims is based upon the product formed and not the method by which it was produced. See In re Thorpe 227 USPQ 964. The burden is upon applicant to submit objective evidence to support their position as to the product-by-process claims. See Ex parte Jungfer 18 USPQ 2D 1796.

In conclusion, it is seen that the claimed product and process of making a calcium containing product are obvious given that the limitations of the claims are shown by the combined references.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

H. Pratt HELEN PRATT PRIMARY EXAMINER

Hp

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